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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,586	04/24/2000	MAURIZIO VALLERI	515-4183	6516

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/463,586	VALLERI, MAURIZIO	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-14 and 17-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *9-12* is/are allowed.

6)☒ Claim(s) *1,3-8,13,14 and 17-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 3-9-05 is acknowledged.

Claims included in the prosecution are 1, 3-14 and 17-22.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"sachet' in claims 19-20 and 'tablet' in claims 21-22 lack an antecedent basis in claim 1.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-8, and 13-14 and 17-22 are rejected under 35 U.S.C. I 03(a) as being unpatentable over FR .2 724 844 to Meignant et al. in view of US Patent 5,576,021 to Andoh et al. OR US Patent 4,493,822 to Tovey 0R Remington's Pharmaceutical Sciences.

Meignant et al. disclose a therapeutic composition of vitamins and calcium, in the form of tablets, comprising elemental calcium and at least one vitamin D. Meignant et al. further teach that the calcium is present in salt form, and can be calcium carbonate, calcium picolate, calcium chloride, calcium glycerophosphate, calcium lactate, calcium citrate, calcium gluconate or calcium phosphate (p l 1, claim 2). Meignant et al. also teach that the vitamin D can be in the form of vitamin D2 or D3 (page 11, claim 3). Additionally, Meignant et al. teach the inclusion of well-known excipients, such as binders, lubricants, diluents, and flavor agents (p 2, 1 20-35). Meignant et al. also teach that the formulation can be in tablet or sachet form (p 13, claim 13). Lastly, Meignant et al. teach a process for making the formulation, including granulating the components and mixing them together, prior to making the final dosage form (p 13, claim 14). Meignant et al. teach 1250 mg of calcium carbonate (which corresponds to 500 mg of elemental calcium) and 4 mg of vitamin 173 (Which corresponds to 400 IU). This fulfills the ratio requirement of applicant's instant claim 1. Instant claim states that the calcium salt must be present in a ratio of 1-2 g of elemental calcium for each 500-1000 IU of vitamin D. Meignant c/ al. teach the identical ratio, as the amounts are simply divided by 2. Therefore, Meignant et al. teach the weight requirements of applicant's instant claims. Meignant et al. do not teach each of the binders claimed by applicant. However, Meignant et al. do teach the presence of a very well known pharmaceutical binder, polyvinyl pyrrolidone.

Andoh et al. teach an improved oral dosage form. This reference is' relied upon for the teachings of equivalency between polyvinyl pyrrolidone and polyethylene glycol as tablet binders. See column 9, claim 4, and column 10, claim 12.

Additionally, Tovey teach pharmaceutical dosage units. Tovey is also relied upon for the teaching of equivalency between polyvinyl pyrrolidone and polyethylene glycol as tablet binders. See column 5, lines 1-13.

Additionally, Remington's Pharmaceutical Sciences discloses a list of binders to be used in pharmaceutical formulations. Remington's teaches polyvinyl pyrrolidone, polyethylene glycol, and waxes. It is the position of the examiner that the disclosure to waxes teaches the equivalency between PVP, PEG, and liquid paraffin. See page 1635, column 2, last 2 paragraphs.

It is the position of the examiner that absent comparative scientific data teaching otherwise, one of ordinary skill in the art would have been motivated to use any well known tablet binder in the composition of Meignant et al., with the same expected result, especially because Meignant et al. teach that their invention is useful for the same purpose of combating osteoporosis as applicant's composition. This is reiterated with the teachings of equivalency provided by Andoh c/ al., Tovey, and Remington's. There has been no comparative evidence provided to convince the examiner that the use of one binder versus another would provide patentable distinction between the instant application and the cited prior art. For the above reasons, this invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments submitted along with the preliminary amendment have been fully considered; however, since the arguments are not based on the rejections made in the previous action, they are not addressed in this action. The declaration of Maurizio Valleri has been considered, but is not found to be persuasive. The evidence presented and conclusions drawn appear to be rather qualitative than based on statistical analysis. For example there is no discussion as to what a 'good dispersion' is. The data presented is rather confusing. First of all, it is unclear why wet granulation method is preformed on components 1-6 represented in col. 1 of Table 1. Secondly, according to the specification (see also instant method claim 13 for example), several other components such as colloidal silica, and sucrose palmitate are also present in the mixture, not just the binder alone. Applicant has not presented any evidence that the properties of the granules would remain the same when these components are present. Thirdly, a proper comparison would be granules obtained under the same process conditions using different binding agents and not comparing granules prepared by different methods. Furthermore, the amounts of the binders used vary drastically and therefore, one cannot make a valid comparison. Fourthly, applicant's claimed range of the molecular weight of PEG is 300-1500 and no data is presented for the upper limit of 1500. Finally, it should be pointed out that the data shown in the declaration indicates that one skilled in the art would be motivated to select the best possible binder from art known binders to obtain a best possible dispersion and the data does not show any results which are unexpected in nature. Applicant has shown no evidence that by using

these specific binders, the calcium absorption is enhanced unexpectedly when administered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK